



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation

Medicines: policy, authorisation and monitoring

PHARM 824

PHARMACEUTICAL COMMITTEE

28 May 2021

Brussels

94th meeting

SUMMARY RECORD

The meeting was organised via video conference and was attended by representatives from the Commission, 26 EU Member States, Norway, the European Medicines Agency (EMA), as well as EU-level representatives of patients, healthcare practitioners, researchers, industry, HTA bodies and public healthcare payers.

The meeting supports the ongoing work with regard to the Pharmaceutical Strategy for Europe. Feedback provided will feed into the evaluation and future proofing of the pharmaceutical framework. It provided a good platform for an active exchange between different stakeholders in areas of key relevance for shaping the future pharmaceutical policy at EU level.

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 822) was adopted.

2. Future proofing: Adapting the legislative framework for medicinal products to support patient centred and need-driven innovation and scientific developments

The session started with a presentation by the European Medicines Agency (EMA) highlighting some of the regulatory challenges stemming from upcoming technologies, novel manufacturing and supply methods and combination products.

During the discussion there was broad stakeholder agreement on the need to uphold double-blind randomised clinical trials as the gold standard for evidence generation. As regards, real world evidence (RWE), it was mentioned that the collection and use only of high quality data should be ensured and that RWE should be viewed as of complementary source of data in pre- and post-authorisation phases. Some stakeholders called for the inclusion of criteria in the revised legislation to ensure use of high quality of RWE post-marketing. Following the experience acquired during the COVID-19 pandemics, the value of RWE to support repurposing and the uptake of new indications was also mentioned.

Participants emphasised the need to increase collaboration on data generation among regulatory agencies, HTA bodies, payers, medical professionals, patients and industry and to provide access to RWE to academic and other non-commercial researchers.

Stakeholders recommended to better regulate decentralised production of products (e.g. gene therapies) with quality production standards. Better use of the digital tools was highlighted and some stakeholders called for digital only product leaflet, which was opposed by other stakeholders, who instead consider it only as a complement to the paper leaflet.

As regards the use of early access schemes and expedited pathways, some stakeholders called for their expansion, while others recommended that these instruments remain the exception rather than the rule and are used exclusively to address unmet medical need. It was also noted that while the rolling review procedure has been very effective during the pandemic, it also creates a high workload for EMA and national competent authorities.

The importance of the EMA fees revision was mentioned in order to ensure that EMA and the national competent authorities are adequately resourced to face such innovative developments.

3. Providing incentives for innovation that reaches the patient

Feedback from the workshop on unmet medical need, which took place on 21 March 2021 involving the Pharmaceutical Committee Members, HTA bodies and payers representatives, was given.

While most of the participants would agree on the need to define criteria (or at least, align the understanding) for identifying products addressing unmet medical need in legislation, divergent views of on the level of details of such criteria were expressed. While some participants supported the need to have strict criteria to clearly identify products which could be rewarded for addressing high societal unmet medical needs; others indicated a preference for the setting up of a set of broad and flexible criteria in order to cater for future innovations. The issues of unmet needs in therapeutic areas where several effective products are already present as well as the involvement of all stakeholders in the determination of unmet medical needs were also raised.

4. Concerning incentives and access, some participants indicated the need to consider new incentives to support developments in specific areas like for the development of novel antimicrobials, or to support repurposed products. Others cautioned on the introduction of novel incentives as the current incentive framework in Europe is already quite generous compared to other regions. Any modification of the existing incentive framework would need to be carefully assessed. The possible linkage of incentives to R&D costs and to timely access in all European markets were also cited.

5. A.O.B.

Next scheduled meeting: Joint meeting of EU Directors for Pharmaceutical Policy & Pharmaceutical Committee (8 and 9 July 2021).